



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 720, 721, 723, and 725**

**[EPA-HQ-OPPT-2013-0385; FRL-9927-79]**

**RIN 2070-AJ98**

**TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct Final Rule.

**SUMMARY:** EPA is taking direct final action to amend the Toxic Substances Control Act (TSCA) section 5 electronic reporting regulations. These electronic reporting regulations establish standards and requirements for use of EPA's Central Data Exchange (CDX) to electronically submit premanufacture notices (PMNs), other TSCA section 5 notices, and support documents to the Agency. This rule provides the user community with new methods for accessing the e-PMN software, new procedures for completing the electronic-PMN (e-PMN) form, changes to the CDX registration process, adds the requirement to submit "*bona fide intents to manufacture*" electronically, and changes to the procedure for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA. This action is intended to further streamline and reduce the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA.

**DATES:** This direct final rule is effective *[insert date 180 days after date of publication in the*

**Federal Register]** without further notice, unless EPA receives adverse comment on or before *[insert date 30 days after date of publication in the **Federal Register]***. If EPA receives adverse comments on this action, EPA will withdraw the rule before its effective date. EPA will then issue a proposed rule, providing a 30-day period for public comment.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0385, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Greg Schweer, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; MC 7405M; telephone number: (202) 564-8469; email address: [Schweer.greg@epa.gov](mailto:Schweer.greg@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-](mailto:TSCA-)

*Hotline@epa.gov.*

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this Action Apply to Me?*

You may be affected by this action if you manufacture (which includes import) or process chemicals for commercial purposes that are subject to TSCA. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide for readers regarding industries within which entities are likely to be affected by this action. Potentially affected entities may include, but are not limited to:

- Manufacturers and processors of chemical substances or mixtures (NAICS codes 325 and 32411).

Full descriptions of these NAICS codes and related establishments are maintained by the U.S. Census Bureau online at <https://www.census.gov/eos/www/naics/index.html>. Other types of entities not listed in this unit could also be affected. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR parts 700, 720, 721, 723, and 725 for TSCA section 5–related obligations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. What Is the Agency's Authority for Taking this Action?*

TSCA gives EPA broad authority to regulate the manufacture (including import) and processing of chemical substances. It is the expressed intent of Congress that EPA carry out TSCA in a reasonable and prudent manner, and in consideration of the impacts that any action taken under TSCA may have on the environment, the economy, and society (TSCA section 2).

The underlying requirements promulgated under this broad authority and amended by this final rule require manufacturers (including importers) and processors of chemical substances and mixtures to:

- Notify EPA at least 90 days before manufacturing a new chemical substance for commercial purposes (TSCA section 5(a)(1)(A)).
- Notify EPA at least 90 days before manufacturing or processing the chemical substance for any use of a chemical substance that EPA has determined to be a “significant new use” (TSCA section 5(a)(1)(B)).

Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer of any new chemical substance from part or all of the provisions of TSCA section 5.

In addition, the Paperwork Reduction Act (PRA) requires Federal agencies to manage information resources to reduce information collection burdens on the public; increase program efficiency and effectiveness; and improve the integrity, quality, and utility of information to all users within and outside an agency, including capabilities for ensuring dissemination of public information, public access to Federal Government information, and protections for privacy and security (44 U.S.C. 3501 *et seq.*).

Finally, the Government Paperwork Elimination Act (GPEA) (Public Law 105–277 (44 U.S.C. 3504)) instructs Federal agencies to use and accept from the public, when practicable, electronic forms, electronic filings, and electronic signatures in the conduct of official business with the public.

### *C. What Action is the Agency Taking?*

This direct final rule amends the TSCA Section 5 Premanufacture and Significant New

Use Notification regulations at 40 CFR parts 720, 721, 723 and 725, by mandating the use of an updated version of the e-PMN reporting software. In the **Federal Register** of January 2010 (75 FR 773) (FRL-8794-5), EPA issued a final rule requiring the use of the e-PMN reporting software for the submission of PMNs and other TSCA section 5 notices and support documents to the Agency using the Internet through CDX. This new version of the e-PMN software will operate as a “cloud” software system (“Thin Client Version”) rather than as a downloadable software system (“Thick Client Version”). In addition, the direct final rule extends electronic reporting requirements to notices of “*bona fide intent to manufacture*” (bona fides); corrects certain regulatory cross-references in 40 CFR parts 720 and 721; standardizes the use of “manufacture” and similar language in 40 CFR parts 720, 721, and 725; and specifies electronic reporting procedures for the notification of new manufacturing sites pursuant to 40 CFR 723.50(j)(6)(ii).

*D. Why is the Agency Taking this Action?*

The Agency is taking this action to further facilitate electronic reporting under TSCA and to streamline and reduce the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA. This change will eliminate certain firewall and file submission size limitations that exist with the current version of the software. This change will also enable submitters to work directly online within the Thin Client Version which provides a more efficient way of accessing the e-PMN software and transmitting data to EPA. In addition, the extension of the electronic reporting requirements ensures that submitters are able to use a single method of submission for related TSCA section 5 notifications.

*E. What are the Impacts of this Action?*

EPA believes that both the transition from the Thick Client Version to the Thin Client

Version of the e-PMN software, as well as the changes to the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50, will streamline and reduce slightly the administrative costs and burdens associated with TSCA section 5 notifications for both industry and EPA; the only burden expected is the time it takes a submitter to familiarize themselves with the rule. EPA believes that submitters of *bona fide intents to manufacture* will experience burden and cost savings because the time required to enter, review, and edit their notices using the e-PMN software and transmit their submissions to EPA electronically will be less than that for the existing paper-based process. See also the discussion in Unit IV.

## **II. Direct Final Rule Procedures**

### *A. Why is EPA Using a Direct Final Rule?*

EPA is publishing this rule without a prior proposed rule because the Agency views this as a noncontroversial action and anticipates no adverse comment. As addressed in Unit I.A., this action requires the use of a new version of the e-PMN software that is easier to access, features enhanced submission security, and eliminates size limitations on the submitted files. The action also corrects certain outdated regulatory cross-references, and standardizes terminology across certain regulatory provisions. If EPA receives adverse comment, the agency will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. If EPA does not receive any timely adverse comment, this amendment will become effective as indicated under **DATES** without any further action by EPA.

### *B. What Should I Consider as I Prepare my Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through <http://www.regulations.gov> or email. Clearly mark the part or all of the information that you

claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

*2. Tips for preparing your comments.* When preparing and submitting any comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

### **III. Overview of the CDX, CISS, and the Thin Client Version of the e-PMN Software**

#### *A. What is CDX?*

CDX is EPA's electronic system for environmental data exchange to the Agency. CDX also provides the capability for submitters to access their data through the use of web services. CDX enables EPA to work with stakeholders, including governments, regulated industries, and the public, to enable streamlined, electronic submission of data via the Internet. For more information about CDX, go to <http://epa.gov/cdx>. TSCA section 5 submissions will be prepared and submitted through Chemical Information Submission System (CISS) in CDX.

#### *B. What is CISS?*

CISS is a web-based reporting tool developed by EPA for use in submitting data, reports, and other information under certain sections of TSCA electronically to the Agency. CISS provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments, or by other electronic standards, such as XML.

### *C. What is the Thin Client Version of the e-PMN Software?*

The thin client version of the e-PMN software is a submission module within CISS. Following promulgation of the e-PMN final rule in 2010, EPA launched submission modules in CISS for TSCA Chemical Data Reporting, TSCA section 4 test data submissions, TSCA section 8(a) preliminary assessment information rules, TSCA section 8(d) health and safety data reporting rules, and mandatory notifications of substantial risk under TSCA section 8(e) along with related, voluntary “For Your Information” submissions. EPA has enhanced the e-PMN software in the thin client version to incorporate several functions already available to submitters in the other CISS submission modules, including:

1. *Enhanced CDX Registration and Submission Process.* When submitters complete new CDX registration activities, they are prompted to choose 5 out of 20 offered questions and provide answers to each of those 5 questions. In order to electronically sign and submit data to the EPA or to download the Copy of Record in CDX, a user must correctly answer 1 randomly selected question of the 5 questions chosen by that user (i.e., a “20-5-1” security question) before the transaction can be completed. When the 20-5-1 security question is answered correctly, the thin client version of the software then encrypts the information and transaction is completed.

2. *Optional online Electronic Signature Agreement (ESA) and identity validation.* The thin client version of the e-PMN software enables electronic submitters who are newly applying for the Authorized Official (AO) role in CDX to validate their personal identities electronically via LexisNexis. Those submitters applying for the AO role who choose to not use LexisNexis, or for whom LexisNexis could not validate their identities, will need to follow the current, paper-based e-PMN identity validation process. In CDX, these submitters will instead select the “Sign Paper Form” option. CDX will then instruct the user to print, sign, and mail the ESA (ESA

processing by EPA may take up to 10 business days from the date of receipt). Since support persons are not able to sign and complete submissions or download the Copy of Record for a submission, they will be able to register with CDX without authentication of identity.

3. *AO Role Expansion.* The role of the AO has been expanded. Not only does the AO of the submitting company certify initial notices and submit all types of section 5 documents to EPA via CDX, the role has been broadened to allow non-certifying AOs (e.g., technical contacts, consultants etc.) to conduct all TSCA section 5 business on behalf of the company except for certifying and submitting initial notices including joint submissions and letters of support. The role for the registered support person has also changed. Support persons will have the ability only to edit information in forms to which they have been granted access by the AO.

4. *Updated user roles/designations.* For joint submissions and/or letters of support, there are new designations/roles assigned in registration referred to as “secondary” (for both AOs and support persons). The “primary” role designation is for persons who will create and submit the main PMN and supporting documents. The “secondary” role designation is for persons who will create and submit joint submissions and letters of support.

#### *D. What are the Benefits of the Thin Client Version of the e-PMN Software?*

EPA developed the Thin Client Version of the e-PMN software to provide a more efficient way of accessing the e-PMN software and completing the e-PMN form. The Thin Client Version of the software was also designed to enable more efficient data transmittal, including increasing the size of files that can be submitted to EPA. By moving from the Thick Client Version of the e-PMN software to the Thin Client Version, the Agency has eliminated the roadblocks associated with firewalls that were encountered by some users of the Thick Client Version by allowing submitters to work directly online within the Thin Client Version or, if they

choose, to work offline using an XML schema which allows them to later upload their information to the Thin Client Version. When preparing and completing submissions in the thin client version, submitters will find that sharing files within the software makes the information readily accessible to registrants of the submitting company and their designated support persons. Also, once a user completes the relevant data fields and attaches appropriate PDF files or other allowable file types, the web-based tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Finally, the Thin Client Version assures that submitters will always use the most up-to-date version of the e-PMN software when initiating, updating, and/or completing their submissions in CISS.

In addition, the thin client version improves EPA data management by altering the process for submitting amendments to a valid notice. Currently, submitters would electronically submit only the amended sections of the form. Under the new procedure, companies will revise the necessary information in the initial notice or a previously modified version of the notice and an entire updated notice will then be resubmitted to EPA. This provides EPA with a complete, updated version of the entire submission in one document.

*E. Will CBI be Protected When using the Thin Client Version of the e-PMN Software?*

Yes. The application has been designed to support TSCA CBI needs by providing a secure environment that meets Federal standards. The application uses Transportation Layer Security with 256-bit digital encryption, and the data is encrypted at rest using a key that only a user knows. All data remains encrypted until it is behind several EPA firewalls and within the EPA CBI LAN, and all encryption algorithms are compliant with Federal Information Processing Standards. In addition, users must have valid CDX credentials (user name and password combination) to access the application, and they choose and provide answers to 5 of the 20

offered questions in CDX. In order to access the CDX account and submit data to the EPA or to download the Copy of Record, a user must correctly answer one of the 5 chosen questions associated with the CDX account.

*F. How Do I Submit TSCA section 5 Notifications and Support Documents Using CDX and the "Thin Client Version" of the e-PMN software?*

EPA has prepared a comprehensive user guide for CISS users that addresses CDX registration and electronic signatures, general submission preparation and completion, and submission status tracking notifications (Ref. 1). This user guide is available through EPA's webpage at <http://www.epa.gov/oppt/chemtest/ereporting>. EPA has also prepared a separate user guide for the e-PMN software module in CISS (i.e., the Thin Client Version) (Ref. 2) which is available through EPA's webpage at <http://epa.gov/oppt/newchems/epmn/epmn-index.htm>.

#### **IV. Description of Changes to Required Reporting Procedures**

*A. What Are the New Requirements for "Bona Fide Intent to Manufacture"?*

This direct final rule extends the electronic reporting requirement to submit PMNs, other TSCA section 5 notices, and support documents to the Agency electronically to include the submissions of bona fides. A person who intends to manufacture a chemical substance not listed by specific chemical name in the public portion of the Inventory of Chemical Substances may ask EPA, through submission of a bona fide intent to manufacture, whether the substance is included in the confidential portion of the Inventory and, thus, be able to determine whether submission of a Premanufacture Notice or Significant New use Notice in accordance with TSCA section 5(a)(1) is required. Bona fides were not included within the scope of the January 2010 final rule due to the variability and frequency of these types of submissions. However, in that rule, EPA stated that this and other types of submissions could be considered for electronic reporting in the future. Bona fides are currently submitted in paper form only according to the

requirements of 40 CFR §720.25, §721.11 and §725.15 which do not prescribe a format, only required content. This direct final rule requires that submitter to submit this information electronically using the Thin Client Version of the e-PMN software.

*B. What Are the New Requirements for Notification of New Manufacturing Sites?*

As required under 40 CFR 723.50(j)(6)(ii), a manufacturer (including importer) must notify EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50. Under the existing regulation, companies may use, but are not required to use, the Notice of Commencement (NOC) to report manufacturing site changes to EPA. Under the existing regulation, however, if the NOC form is used for this purpose, the manufacturer must add a statement to the NOC form that the notification is an amendment to the original exemption. The electronic version of the NOC in the e-PMN software has been designed to solely deal with NOCs and will not accommodate notifications of manufacturing site changes. Therefore, this direct final rule requires that such notifications of changes in manufacturing sites be submitted electronically to EPA via CDX as a “support document” to the original notification.

*C. How Has the Required Method of Submission Changed?*

EPA’s electronic reporting program has evolved significantly following the promulgation of the e-PMN final rule in 2010. Following promulgation of that rule, EPA announced web-based electronic reporting workflows for TSCA Chemical Data Reporting, TSCA section 4 test data submissions, TSCA section 8(a) preliminary assessment information rules, TSCA section 8(d) health and safety data reporting rules, and mandatory notifications of substantial risk under TSCA section 8(e) along with related, voluntary “For Your Information” submissions.

Under the current e-PMN rule requirements, TSCA section 5 submitters already must

register in CDX and complete an electronic signature agreement before submitting any information to EPA electronically via CDX using the e-PMN software. This direct final rule requires all persons who will be working online on a submission to register with EPA's CDX and to use the e-PMN module within CISS to prepare data for submission. EPA expects that most TSCA section 5 submitters are already registered in CDX. Those users do not need to re-register with CDX, nor will they need to re-verify their identities. In order to use the Thin Client Version of the e-PMN software required under this direct final rule, users who have previously registered with CDX under the TSCA workflow to submit TSCA section 5 submissions, or other CDX workflows such as the Toxics Release Inventory TRI-ME web reporting, will only need to add the "Submission for Chemical Safety and Pesticide Program (CSPP)" CDX workflow to their user profiles.

*D. Will EPA Offer Any Exceptions to the Transition to the Thin Client Version?*

No. The Agency has concluded that the overall benefits from everyone using the more efficient Thin Client Version of the e-PMN software and submission through CDX exceed those associated with maintaining a multi-optioned reporting approach (Ref. 3). The Agency recognizes that there is the potential for costs and burden associated with unpredictable or unanticipated technical difficulties in electronic filing or with the conversion to the "Thin Client Version." However, EPA expects that the transition costs and any transition difficulties will be mitigated by:

1. EPA's planned outreach and training sessions prior to the effective date of this direct final rule. EPA believes that the six-month phase-out period for the Thick Client Version between the date of publication and the effective date of this direct final rule provides submitters with ample time to register to use and become proficient with the Thin Client Version of the e-

PMN software. EPA will accept submissions using the Thin Client Version of the e-PMN software beginning on *[insert date 45 days after publication in the **Federal Register**]*. After *[insert date 180 days after publication in the **Federal Register**]*, use of the Thin Client Version of the e-PMN software becomes mandatory.

2. EPA’s offering of an XML schema to those submitters who choose to work on their submissions offline rather than online, which allows them to later upload their information to the Thin Client Version of the e-PMN software for submission using CDX. The six-month phase-out period for the period between the date of publication and the effective date of the final rule should provide these users adequate time to implement the XML schema on their systems.

3. EPA’s technical support following the effective date of this final rule.

*E. Will All Types of TSCA section 5 Notices and Communications be submitted via e-PMN Software?*

At this time, the Agency lacks electronic reporting capability for some TSCA section 5-related notices (e.g., polymer exemption annual reports); certain support documents (i.e., TSCA section 5(e) consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)); and certain communications (e.g., pre-notice communications and TSCA Inventory correspondence), due to the variability and infrequent nature of these types of submissions. EPA may consider offering electronic reporting of these and other submissions in the future.

## **V. Corrections to 40 CFR Parts 720, 721, 723 and 725**

The direct final rule also corrects certain regulatory cross-references in 40 CFR parts 720 and 721 and standardizes the use of “manufacture” and similar language in 40 CFR parts 720, 721, and 725.

1. *Minor change to definition of “article” in 40 CFR 720.3.* The current definition of “article” at 40 CFR 720.3(c) incorrectly references 40 CFR 720.36(g)(5) concerning changes in

chemical composition which have no commercial purpose separate from that of the article. This rulemaking corrects the cross-reference to 40 CFR 720.30(h)(5).

2. *Removal of the cross-reference to 40 CFR 710.7(e)(2)(v) in 40 CFR 720.25(b)(4) and 40 CFR 721.11(d).* The CFR at § 720.25(b)(4) and § 721.11(d) currently cross-references both 40 CFR 710.7(e)(2)(v) and 40 CFR 720.85(b)(3)(iii). These cross-references should only be to 40 CFR 720.85(b)(3)(iii); 40 CFR 710.7(e)(2)(v) no longer exists.

3. *Use of “manufacture or import” and similar language in 40 CFR 720.25(b), 40 CFR 721.11 and 40 CFR 725.15.* The definition of “manufacture” in section 3(7) of TSCA includes both manufacture and import. However, in many places in TSCA section 5 regulations in parts 720, 721, 725 and elsewhere the terms “manufacture or import” or “manufacture, import or process” are used. EPA is revising “manufacture” and “manufacturer” in some of the provisions affected by this rule to clarify that import is included in manufacture under TSCA. This is not intended to make any substantive change to the regulations. As EPA amends other TSCA regulations with similar language in the future, the Agency intends to make corresponding changes.

4. *Removal of the definition of “optical disc” in 40 CFR 720.3.* The January 2010 (75 FR773) final rule phased out the electronic submission of TSCA section 5 notices to EPA via optical disc as a valid method of submission as of April 6, 2012. Therefore, the definition currently presented at 40 CFR 720.3(kk) is obsolete and will be removed.

5. *Use of CDX to submit written requests for suspension of the notice review period in 40 CFR 720.75.* The January 2010 final rule phased out paper submissions of TSCA section 5 notices to EPA as of April 6, 2011, and the electronic submission of TSCA section 5 notices to EPA via optical disc as a valid method of submission as of April 6, 2012. However, 40 CFR

720.75(b)(4) continues to provide that written requests for suspension of the notice review period may be submitted to EPA on paper, on optical disc, or in CDX. This final rule corrects 40 CFR 720.75 to specify that written suspension requests must be submitted to EPA via CDX.

## **VI. Estimated Economic Impact**

The Agency's estimated economic impact of this direct final rule is presented in a document entitled "Economic Analysis of the TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations" (Economic Analysis) (Ref. 3), a copy of which is available in the docket and is briefly summarized in this unit. In the economic analysis supporting the January 6, 2010 (75 FR 773) e-PMN final rule, EPA estimated that the electronic submission of TSCA section 5 notices and support documents would reduce the burden and cost associated with the paper-based reporting process of TSCA section 5 notices and support documents (Ref. 4). This direct final rule amends the existing premanufacture notification regulation to mandate the use of the Thin Client Version of the e-PMN reporting software, require use of electronic reporting of TSCA section 5 bona fides, and amends the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50. These amendments are expected to further streamline and reduce the administrative costs and burdens associated with TSCA section 5 notifications for both industry and EPA.

The Thin Client Version of the e-PMN software will reside as a module within CISS in CDX. The Thin Client Version will eliminate certain firewall and file submission size limitations, as well as reduce the potential for invalid submissions through built-in validation procedures. Use of the Thin Client Version also assures that should revisions be made by EPA, submitters will always use the most up-to-date version of the e-PMN software when initiating,

updating, and/or completing their submission in CISS.

Making the software available to industry is expected to result in cost savings for both industry and EPA. However, this direct final rule, which includes a new requirement for electronic submission of bona fide notices and changes to the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50, may result in some temporary increase in cost to some industry users as they make the transition to the new method of submission. As a result of making the software available, EPA believes that submitters of bona fide notices will experience burden and cost savings because the time required to enter, review, and edit their notices using the e-PMN software and transmit their submissions to EPA electronically will be less than that for the existing paper-based process. In EPA's economic analysis (Ref. 3), estimated burden and cost savings are presented in comparison to the burden and costs that will be incurred if industry were to continue submitting notices via paper, as was outlined in the previous Information Collection Request (ICR) (Ref. 5). OMB has already approved the underlying information collection requirements described in this direct final rule under OMB control numbers 2070-0012 and 2070-0038 (EPA Information Collection Request (ICR) No. 0574.15, *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (Ref. 5) and EPA ICR No. 1188.11, *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (Ref. 6)), respectively. EPA has submitted requests for additional approval to OMB under PRA (Refs. 8 and 9) because the direct final rule alters the required form and format of the existing, approved collections of information.

Once the rule is fully implemented, EPA estimates a net burden savings to industry of 180 hours and a net cost of approximately \$4,000 in the first year. In subsequent years, EPA estimates an annual net burden savings to industry of 489 hours and annual net cost savings of approximately \$17,000. The Agency is projected to experience an annual net burden savings of 40 hours and annual net cost savings of \$3,000 for these same submissions once the rule is fully implemented.

Requiring use of the e-PMN software for submission of bona fides (40 CFR 720.25, 40 CFR 721.11 and 40 CFR 725.15), suspension requests (40 CFR 720.75), and changes in manufacturing sites (40 CFR 723.50(j)(6)) eliminates the option of submitting paper. To the extent that any firms would otherwise submit these notices on paper, these firms may incur some costs in order to meet these mandatory submission requirements. For example, some industry users may incur costs related to adjustments to internal processes or recordkeeping systems, and investments in compatible information technology. At this time, EPA is unable to estimate what these costs might be. However, firms have generally been required to file section 5 notifications electronically using the e-PMN software since April 2012, and a final rule published in the **Federal Register** of December 4, 2013(78 FR 72818) (FRL-9394-6) requires that any new NOCs for PMNs filed in paper prior to April 2012 be submitted electronically using the e-PMN software (Ref. 7). Firms expected to submit bona fides, suspension requests, and changes in manufacturing sites are believed by EPA to primarily be the same firms that are already complying with the existing regulations. EPA therefore does not believe that many, if any, firms would incur such costs only for the electronic submission of bona fides or notifications of manufacturing site changes for a previously submitted PMN.

The total annual burden to society (industry plus EPA) from the e-PMN software is

expected to decrease by 57 hours in the first year and 529 hours in subsequent years. The total cost to society is expected to increase by \$1,000 in year one and decrease by \$20,000 in future years. These cost savings may be diminished by any transactions costs that firms compelled to switch to the new software system might face for submission of bona fides. EPA believes that both the transition from the Thick Client Version to the Thin Client Version, as well as the changes to the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50, will have a negligible impact on industry or Agency burden or costs, and, therefore, the cost savings associated with these changes are only described qualitatively in the Economic Analysis (Ref. 3).

## **VII. References**

The public docket for this final rule has been established. The following is a listing of the documents referenced in this preamble that have been placed in the public docket for this final rule under docket ID number EPA-HQ-OPPT-2013-0385, which is available for inspection as specified under **ADDRESSES**.

1. EPA. Central Data Exchange CSPP CDX Registration Guide, December 12, 2011.
2. EPA. Section 5 Notices and Supports Users Guide. December 20, 2013 (available at: <http://www.epa.gov/oppt/newchems/epmn/epmn-index.htm>).
3. EPA. Economic and Policy Analysis Branch, Office of Pollution Prevention and Toxics (OPPT). Economic Analysis of the TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revision to Notification Regulations. November 17, 2014.
4. EPA. Economic and Policy Analysis Branch, Office of Pollution Prevention and Toxics (OPPT). Economic Analysis of the Amendments to TSCA Section 5 Premanufacture and

Significant New Use Notification Requirements Final Rule. July 13, 2009.

5. EPA Information Collection Request (ICR) No. 0574.15, Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances.

6. EPA ICR No. 1188.12, TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals.

7. EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule.

**Federal Register** (78 FR 72818, December 4, 2013) (FRL–9394-6).

8. EPA. Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act. Revision to Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (Direct Final Rule; RIN 2070-AJ98). EPA ICR No. 0574.16. OMB Control Number 2070–0012.

9. EPA. Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act. Request for a Non-Substantive Change to an Existing Approved Information Collection, TSCA Section 5(a)(2) Significant New Use rules for Existing Chemicals. EPA ICR No. 1188.12; OMB Control Number 2070-0038.

## **VIII. Statutory and Executive Order Reviews**

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is not a significant regulatory action as defined by Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, this action was not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). EPA has prepared an Economic Analysis for this action (Ref. 3), which

is available in the docket for this final rule and is summarized in Unit VI.

*B. Paperwork Reduction Act*

The information collection activities in this direct final rule been submitted for approval to OMB under the PRA (44 U.S.C. 3501 *et seq.*) pursuant to the procedures at 5 CFR 1320.5(c)(1) and 1320.10(a). The underlying requirements are approved under OMB control numbers 2070-0012 and 2070-0038. However, EPA has submitted requests for additional approval to OMB under PRA because the direct final rule alters the required form and format of the existing, approved collections of information.

The Information Collection Request (ICR) document that EPA prepared to address the direct final rule requirements related to EPA's New Chemicals Program has been assigned EPA ICR number 0574.16 (Ref. 8). This ICR addresses the required use of the Thin Client version of the e-PMN software system in CDX to complete their TSCA section 5 submissions to EPA's New Chemicals Program instead of a downloadable Thick Client version of the e-PMN software system. In addition, this ICR addresses the mandatory electronic submission of bona fide notices and notifications of new manufacturing sites of chemical substances for which an exemption was granted by EPA under 723.50.

As addressed in EPA ICR No. 0574.16, the total burden to industry is expected to decrease 182 hours and the total cost is expected to increase by \$3,988 in the first year of the rule, for a total burden of 2,312 hours and \$155,699. This includes an average per firm burden of 0.82 hours for rule familiarization for 336 TSCA section 5 submitters, a per-submission burden of 17.0 hours for electronic reporting of 116 bona fide submissions, a per-registrant burden 0.43 hours for 93 new technical labor CDX registrations, and a-per registrant burden of 1.07 hours for 23 new managerial CDX registrants. In all subsequent years of the rule the total industry burden

is expected to decrease by 485 hours and \$17,199. This includes a per submission burden of 17.0 hours for electronic reporting of 116 bona fide submissions, a per-registrant burden 0.43 hours for 46 new technical labor CDX registrations, and a per-registrant 1.07 hours for 12 new managerial CDX registrants.

In addition, EPA has been assigned EPA ICR number 1188.12 (Ref. 9) to the ICR document that addresses the direct final rule requirements related EPA's Existing Chemicals Program (i.e., the required use of the Thin Client version of the e-PMN software system in CDX to complete their TSCA section 5 submissions to EPA's Existing Chemicals Program instead of a downloadable Thick Client version of the e-PMN software system). The direct final rule would only require firms who must already submit significant new use notices for existing chemicals to use the new electronic reporting tool. EPA, therefore, did not estimate any rule-related burden changes for this ICR.

You can find a copy of these ICR documents in the docket for this direct final rule. Any comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden must be to the EPA using the docket identified at the beginning of this direct final rule by *[insert date 30 days after date of publication in the **Federal Register**]*. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oria\_submissions@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than *[insert date 30 days after date of publication in the **Federal Register**]*.

Responses to the collection of information are mandatory, pursuant to EPA's authority under TSCA and PRA (as described in Unit I.C.). However, the changes to the information

collection requirements in this direct final rule are not enforceable until OMB approves them. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

### *C. Regulatory Flexibility Act*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C § 601 *et seq.* In making this determination, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of a final regulatory flexibility analysis is to identify and address regulatory alternatives that “minimize the significant economic impact on small entities” 5 U.S.C. 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden effect on the small entities subject to the rule.

As indicated previously, this final rule is expected to reduce the existing regulatory burden. The factual basis for the Agency's certification under the RFA is presented in the small entity impact analysis prepared as part of the Economic Analysis for this final rule (Ref. 3), and is briefly summarized in Unit IV.

### *D. Unfunded Mandates Reform Act and Executive Orders 13132 and 13175*

This action will not have substantial direct effects on State, local, or tribal governments, on the relationship between the Federal Government and States or Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and States or Indian Tribes. As a result, no action is required under Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), or under Executive Order 13175, entitled “Consultation and

Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Nor does it impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531-1538).

*E. Executive Orders 13045, 13211, and 12898*

As indicated previously, this action is not a “significant regulatory action” as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) and Executive Order 13211 entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). In addition, this action also does not require any special considerations under Executive Order 12898 entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

*F. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

**IX. Congressional Review Act**

Pursuant to the CRA, 5 U.S.C. 801 *et seq.*, EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Parts 720, 721, 723, and 725**

Environmental protection, Chemicals, Electronic reporting, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 10, 2015.

Louise P. Wise,

*Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 720—[AMENDED]**

1. The authority citation for part 720 continues to read as follows:

**Authority:** 15 U.S.C 2604, 2607, and 2613.

2. In § 720.3:

- a. Revise paragraph (c).
- b. Remove paragraph (kk).
- c. Redesignate paragraph (ll) as (kk).
- d. Revise newly redesignated paragraph (kk).

The revisions read as follows:

**§ 720.3 Definitions.**

\* \* \* \* \*

(c) *Article* means a manufactured item:

(1) Which is formed to a specific shape or design during manufacture;

(2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design.

\* \* \* \* \*

(kk) *Support documents* means material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence, amendments (if notices

for these amendments were submitted prior to [*insert date 180 days after date of publication in the Federal Register*]), and test data. The term “support documents” does not include orders under TSCA section 5(e) (either consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)).

3. In § 720.25, revise paragraphs (b)(1), (b)(2) introductory text, (b)(2)(i) and (ii), and (b)(4), (5), (6), and (7) to read as follows:

**§ 720.25 Determining whether a chemical substance is on the Inventory.**

\* \* \* \* \*

(b) \* \* \*

(1) A chemical substance is listed in the public portion of the Inventory by a specific chemical name (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name) and a Chemical Abstracts Service (CAS) Registry Number if its identity is not confidential. If its identity is confidential, it is listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. The confidential substance is listed by its specific chemical name only in the confidential portion of the Inventory, which is not available to the public. A person who intends to manufacture (including import) a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture (including import) the chemical substance for commercial purposes.

(2) To establish a *bona fide* intent to manufacture (including import) a chemical substance, the person who proposes to manufacture the substance must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such *bona fide* intents to manufacture

(including import) must be generated and completed using e-PMN software. See § 720.40(a)(2)(ii) for information on how to access the e-PMN software. A *bona fide* intent to manufacture (including import) must contain:

(i) Except as provided in paragraphs (b)(3)(i) and (ii) of this section, the specific chemical identity of the substance that the person intends to manufacture (including import), using the currently correct CA Index name for the substance and the other correct chemical identity information in accordance with § 720.45(a) (1), (2), and (3).

(ii) A signed statement that the person intends to manufacture (including import) that chemical substance for commercial purposes.

\* \* \* \* \*

(4) EPA will review the information submitted by the proposed manufacturer (including importer) under this paragraph to determine whether it has a *bona fide* intent to manufacture (including import) the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under § 720.85(b)(3)(iii).

(5) If the proposed manufacturer (including importer) has shown a *bona fide* intent to manufacture (including import) the substance, and has provided sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's Inventory status, EPA will search the confidential Inventory and inform the proposed manufacturer (including importer) whether the chemical substance is on the confidential Inventory.

(6) If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a *bona fide* intent to manufacture (including import) the substance and therefore was told that the

chemical substance is on the Inventory.

(7) A disclosure of a confidential chemical identity to a person with a *bona fide* intent to manufacture (including import) the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.

\* \* \* \* \*

4. In § 720.40, revise paragraphs (a)(2)(i), (a)(2)(ii) introductory text, and (e)(1) and (3) to read as follows:

**§ 720.40 General.**

(a) \* \* \*

(2) \* \* \*

(i) *Submission via CDX.* TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710-25 using e-PMN software.

(ii) You can access the e-PMN software as follows:

\* \* \* \* \*

(e) *Agency or joint submissions*—(1) A manufacturer (including importer) may designate an agent to assist in submitting the notice. If so, only the manufacturer (including importer), and not the agent, signs the certification on the form.

(2) \* \* \*

(3) Only the Authorized Official (AO) of a submitting company can certify initial notices and submit all TSCA section 5 documents.

(i) An AO can authorize other persons to be non-certifying AOs who may conduct all section 5 business on behalf of the submitting company except for certifying and submitting

initial notices to EPA via CDX.

(ii) An AO may grant access to a support registrant to edit section 5 documents.

\* \* \* \*

5. In § 720.75:

a. Revise paragraph (b)(2).

b. Remove paragraphs (b)(3) and (4).

c. Revise paragraph (e)(2).

The revisions read as follows:

**§ 720.75 Notice review period.**

\* \* \* \*

(b) \* \* \*

(2)(i) *Oral requests.* A request for a suspension of 15 days or less may be made orally, including by telephone, to the submitter's EPA contact for that notice. Any request for a suspension exceeding 15 days must be submitted in the manner set forth in paragraph (b)(2)(ii) of this section. The running of the notice review period will be suspended upon approval of the oral request by the Director or her or his delegate.

(ii) *Written requests.* Requests for suspensions exceeding 15 days must be submitted electronically to EPA via CDX using e-PMN software. Requests for suspensions of 15 days or less may also be submitted electronically to EPA via CDX using e-PMN software. See §720.40(a)(2)(ii) for information on how to access the e-PMN software. The running of the notice review period will be suspended upon approval of the written request by the Director or her or his delegate.

\* \* \* \*

(e) \* \* \*

(2) If a manufacturer (including importer) which withdrew a notice later resubmits a notice for the same chemical substance, a new notice review period begins.

**PART 721--[AMENDED]**

6. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

7. In § 721.11, revise paragraphs (a), (b) introductory text, (b)(1), (2), and (3), (d), (e) and (f) to read as follows:

**§ 721.11 Applicability determination when the specific chemical identity is confidential.**

(a) A person who intends to manufacture (including import) or process a chemical substance which is described by a generic chemical name in subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture (including import) or process the chemical substance for commercial purposes.

(b) To establish a *bona fide* intent to manufacture (including import) or process a chemical substance, the person who proposes to manufacture (including import) or process the substance must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such *bona fide* intents to manufacture (including import) or process must be generated and completed using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software. A *bona fide* intent to manufacture (including import) or process must contain:

(1) The specific chemical identity of the chemical substance that the person intends to manufacture (including import) or process.

(2) A signed statement that the person intends to manufacture (including import) or

process the chemical substance for commercial purposes.

(3) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture (including import) or process the chemical substance.

\* \* \* \* \*

(d) EPA will review the information submitted by the manufacturer (including importer) or processor under paragraph (b) of this section to determine whether that person has shown a bona fide intent to manufacture (including import) or process the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under § 720.85(b)(3)(iii) of this chapter.

(e) If the manufacturer (including importer) or processor has shown a *bona fide* intent to manufacture (including import) or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer (including importer) or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies.

(f) A disclosure to a person with a *bona fide* intent to manufacture (including import) or process a particular chemical substance that the substance is subject to this part will not be considered public disclosure of confidential business information under section 14 of the Act.

\* \* \* \* \*

## **PART 723—[AMENDED]**

8. The authority citation for part 723 continues to read as follows:

**Authority:** 15 U.S.C. 2604.

9. In § 723.50:

- a. Revise paragraph (j)(6)(ii)(B).
- b. Remove paragraph (j)(6)(ii)(C).

The revision reads as follows:

**§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.**

\* \* \* \*

(j) \* \* \*

(6) \* \* \*

(ii) \* \* \*

(B) The notification must be submitted electronically to EPA via CDX as a support document to the original notification. Prior to submission to EPA via CDX, such notices must be generated and completed using the e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software.

\* \* \* \*

**PART 725—[AMENDED]**

10. The authority citation for part 725 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, 2613 and 2625.

11. In § 725.15, revise paragraphs (a)(2), (b)(2) introductory text, (b)(2)(ii) and (iii), (d), (e), (f), and (g) to read as follows:

**§725.15 Determining applicability when microorganism identity or use is confidential or uncertain.**

(a) \* \* \*

(2) Uncertain microorganism identity. The current state of scientific knowledge leads to some imprecision in describing a microorganism. As the state of knowledge increases, EPA will be developing policies to determine whether one microorganism is equivalent to another. Persons intending to conduct activities involving microorganisms may inquire of EPA whether the microorganisms they intend to manufacture (including import) or process are equivalent to specific microorganisms described on the Inventory, in §725.239, or in subpart M of this part.

(b) \* \* \*

(2) To establish a *bona fide* intent to manufacture (including import) or process a microorganism, the person who proposes to manufacture (including import) or process the microorganism must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such *bona fide* intents to manufacture (including import) or process must be generated and completed using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software. A *bona fide* intent to manufacture (including import) or process must contain the following information:

\* \* \* \* \*

(ii) A signed statement certifying that the submitter intends to manufacture (including import) or process the microorganism for commercial purposes.

(iii) A description of research and development activities conducted with the microorganism to date, demonstration of the submitter's ability to produce or obtain the microorganism from a foreign manufacturer, and the purpose for which the person will manufacture (including import) or process the microorganism.

\* \* \* \* \*

(d) EPA will review the information submitted by the manufacturer (including importer)

or processor under this paragraph to determine whether that person has shown a *bona fide* intent to manufacture (including import) or process the microorganism. If necessary, EPA will compare this information to the information requested for the confidential microorganism under §725.85(b)(3)(iii).

(e) In order for EPA to make a conclusive determination of the microorganism's status, the proposed manufacturer (including importer) or processor must show a *bona fide* intent to manufacture (including import) or process the microorganism and must provide sufficient information to establish identity unambiguously. After sufficient information has been provided, EPA will inform the manufacturer (including importer) or processor whether the microorganism is subject to this part and if so, which sections of this part apply.

(f) If the microorganism is found on the confidential version of the Inventory, in §725.239 or in subpart M of this part, EPA will notify the person(s) who originally reported the microorganism that another person (whose identity will remain confidential, if so requested) has demonstrated a *bona fide* intent to manufacture (including import) or process the microorganism and therefore was told that the microorganism is on the Inventory, in §725.239, or in subpart M of this part.

(g) A disclosure to a person with a *bona fide* intent to manufacture (including import) or process a particular microorganism that the microorganism is on the Inventory, in §725.239, or in subpart M of this part will not be considered a public disclosure of confidential business information under section 14 of the Act.

\* \* \* \* \*